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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/777,640	02/07/2001	Babak Nemati		4426

7590 05/15/2003
Suzannah K Sundby
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The Jenifer Building
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Washington, DC 20004-2201

EXAMINER

HAYES, MICHAEL J

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 05/15/2003

10

Please find below and/or attached an Office communication concerning this application or proceeding.

N.K.

Office Action Summary

Application No.

09/777,640

Applicant(s)

NEMATI, BABAK

Examiner

Michael J Hayes

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 37-69 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 37-69 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 07 February 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 37-56, 62, and 69 are rejected under 35 U.S.C. 102(b) as being anticipated by MARTINEZ (U. S. Patent No. 4,222,375). Martinez discloses an apparatus capable of enhancing the optical transparency of biological tissue comprising means for bypassing the surface barrier (needle), means for delivering clarifying agent (syringe), means for delivery of light (fiber optic cable). The various uses recited in the claims are readable on the prior art because the prior art is capable of performing these functions and supplying light for these functions.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 37-52, 54-56, 62-64, 66, and 69 are rejected under 35 U.S.C. 103(a) as being obvious in view of CHAN et al. (6,275,726). Chan discloses means for bypassing the surface permeability barrier of tissue, means for delivering a clarifying agent, and means of light delivery for diagnostic and therapeutic applications (1:50-65; 2:24-32; 3:51-67; 4:1-12; 7:36-63; 8:37-40). The various skin appendages will inherently be affected when the agent is injected into the tissue. Chan does not disclose the various parts to be used in one apparatus; however, it is

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well within the knowledge of the skilled artisan to make that which comprises plural parts into one part to simply the use of a device.

Claims 53, 57-59, 61, 65, and 67 are rejected under 35 U.S.C. 103(a) as being unpatentable over MARTINEZ as applied to claims 37 and 38 above, and further in view of EDWARDS (U. S. Patent No. 5,833,647). Martinez discloses the claimed invention except for bypassing means including iontophoresis system, electric pulse generator, acoustic generator, and temperature gradient. Edwards teaches using these methods which inherently require the appropriate systems and generators to drive molecules. It would have been obvious to one of ordinary skill in the art at the time of the invention to use the teachings of Edwards in the invention of Martinez in order to deliver the agent across the skin barrier.

Claims 60 and 68 are rejected under 35 U.S.C. 103(a) as being unpatentable over MARTINEZ as applied to claim 37 above, and further in view of WEAVER (U. S. Patent No. 5,019,034). Martinez discloses the claimed invention except for bypassing means to apply optical pressure and penetrating solvent. Weaver teaches the use of means to apply optical pressure and penetrating solvent for transdermal delivery. It would have been obvious to one of ordinary skill in the art at the time of the invention to facilitate delivery of an agent across the skin barrier.

Response to Arguments

Applicant's arguments with respect to claims 37-69 have been considered but are moot in view of the new ground(s) of rejection.

Applicant should note that the examiner considers the newly added limitation of one apparatus as an obvious variant to the prior art. Specifically, making something into one

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apparatus that was previously comprised of two apparatus would be obvious to one of ordinary skill in the art at the time of the invention. The mere combining of the apparatus without a more specific recitation of the structural relationship between the parts would be obvious to one of ordinary skill in the art. Apparatus consists of several parts and the addition of more parts whose function was disclosed in the prior art to be used with the original apparatus would be obvious to the skilled artisan.

Conclusion

If Applicant desires an interview he should contact the examiner at the number below to arrange a date and time.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Hayes at (703) 305-5873. The examiner can usually be reached Monday -Thursday, 7:00-4:30, and on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler, can be contacted at (703) 308-3552. The fax number for submitting official papers is (703) 872-9302. The fax number for submitting after final papers is (703) 872-9303.

mjh
12 May 2003

A handwritten signature in black ink that reads "Michael J. Hayes". The signature is written in a cursive, flowing style.

MICHAEL J. HAYES
PRIMARY EXAMINER